UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION This document relates to: *County of Summit, Ohio, et al. v. Purdue Pharma L.P., et al.* Case No. 1:18-OP-45090 *The County of Cuyahoga v. Purdue Pharma L.P., et al.* Case No. 17-OP-45004	MDL No. 2804 Case No. 17-md-2804 Hon. Dan Aaron Polster

MEMORANDUM OF LAW IN SUPPORT OF MANUFACTURER DEFENDANTS' MOTION FOR SUMMARY JUDGMENT THAT PLAINTIFFS' STATE-LAW CLAIMS ARE PREEMPTED AND THEIR FEDERAL CLAIMS ARE PRECLUDED

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INTRODUCTION

The federal Food and Drug Administration ("FDA"), pursuant to the federal Food, Drug, and Cosmetic Act ("FDCA"), has approved numerous opioid medications for long-term treatment of chronic, non-cancer pain. As recently as last month, the FDA again considered and rejected suggestions that those prescription opioids are unsafe or should be limited in duration or dose. The FDA instead recognized that opioid medications are an important tool in managing chronic pain, a condition which affects quality of life and carries with it numerous other health consequences. The Drug Enforcement Administration ("DEA"), pursuant to the federal Controlled Substances Act ("CSA"), has in turn set quotas for the permissible sales of these prescription opioid medications. Despite these clear FDA and DEA actions, and notwithstanding Plaintiffs' prior protestations to the contrary, discovery has now made clear that Plaintiffs seek to up-end the careful determinations of these federal agencies and to hold the Manufacturers[1] liable for the very actions these agencies approved. But under U.S. Supreme Court precedent, such state-law claims are preempted, and Plaintiffs' federal claims are similarly precluded because they conflict with

[1] "Manufacturers" refers to Purdue Pharma, L.P., Purdue Pharma, Inc., The Purdue Frederick Company, Inc., Endo Health Solutions Inc., Endo Pharmaceuticals Inc., Par Pharmaceutical, Inc., Par Pharmaceutical Companies, Inc. (incorrectly named as "Par Pharmaceutical Companies, Inc. f/k/a Par Pharmaceutical Holdings, Inc.), Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., n/k/a Janssen Pharmaceuticals, Inc., Johnson & Johnson, Noramco, Inc., Teva Pharmaceutical Industries Ltd., Teva Pharmaceuticals USA, Inc, Cephalon, Inc., Allergan plc f/k/a Actavis plc, Allergan Finance, LLC, f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc., Allergan Sales, LLC, Allergan USA, Inc., Watson Laboratories, Inc., Actavis LLC, Actavis Pharma, Inc. f/k/a Watson Pharma, Inc, Mallinckrodt, plc, Mallinckrodt LLC, SpecGx LLC, Allergan Sales, LLC, Allergan USA, Inc., Warner Chilcott Company, LLC, Actavis South Atlantic LLC, Actavis Elizabeth LLC, Actavis Mid Atlantic LLC, Actavis Totowa LLC, Actavis Kadian LLC, Actavis Laboratories UT, Inc. f/k/a Watson Laboratories, Inc.-Salt Lake City, and Actavis Laboratories FL, Inc., f/k/a Watson Laboratories, Inc.-Florida. Teva Pharmaceutical Industries Ltd., Allergan plc, and Mallinckrodt plc are respectively an Israeli corporation, Irish holding company, and Irish company that are not subject to and contest personal jurisdiction for the reasons explained in their pending motions to dismiss for lack of personal jurisdiction, they are specially appearing to join this motion as a result of the Court's deadline to file dispositive and Daubert motions, and, thus, they do not waive and expressly preserve their pending personal jurisdiction challenges. On June 10, 2019, Insys Therapeutics, Inc. and its affiliates each filed a voluntary case under chapter 11 of United States Bankruptcy Code in the United States Bankruptcy Court for the District of Delaware, which cases are being jointly administered under Case No. 19-11292 (KG). In light of this bankruptcy proceeding, Insys does not join any of the Daubert motions or summary judgment motions to be filed in the MDL Track One cases.

and seek to undermine the balance struck by the FDCA and the CSA.

First, discovery has now made clear that Plaintiffs seek to hold the Manufacturers liable for marketing opioid medications for the long-term treatment of chronic, non-cancer pain. But labeling and marketing activities are carefully regulated by the FDA, and as the U.S. Supreme Court reiterated just last month, federal law preempts state-law claims where there is "'clear evidence' that the FDA would not have approved the warning that state law requires." *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1676 (2019) (citing *Wyeth v. Levine*, 555 U.S. 555, 571 (2009)).[2] Such "clear evidence" exists here. The FDA previously rejected the very changes in labeling and prescribing that Plaintiffs' experts claim the Manufacturers should have made, including that opioid medications should not have been marketed for long-term treatment of chronic, non-cancer pain and that dose and duration limitations should have been set.

Indeed, as recently as ***last*** month, the FDA further cautioned that:

> It is important to consider the potential repercussions of well-meaning attempts to address the opioid crisis without adequate scientific evidence to support such actions. Inadequately treated chronic pain has consequences . . . . Robust evidence supports that chronic pain itself, regardless of type, is an important independent risk factor for suicidality . . . .[3]

Given this and other "clear evidence," federal law preempts Plaintiffs' state-law claims asserting that the Manufacturers inappropriately labeled and marketed their opioid medications for long-term treatment of chronic, non-cancer pain.[4] And while Plaintiffs' RICO claims are federal and

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[2] Unless otherwise noted, quotations and citations are omitted throughout.

[3] *See* Ex. 1 (May 13, 2019 Mem. re Opioids Regulatory Background, FDA Center for Drug Evaluation and Research ("May 2019 FDA Mem.") at 10 (declining to recommend limits on doses for prescription opioid medications)). All exhibits referenced herein are exhibits to the Declaration of Jonathan L. Stern in Support of Manufacturer Defendants' Motion for Summary Judgment that Plaintiffs' State-Law Claims Are Preempted and Their Federal Claims Are Precluded.

[4] While certain opioids were only approved by the FDA for indications unrelated to the long-term treatment of chronic pain, Plaintiffs do not have any evidence that the Manufacturers of those medications were improperly promoting them for long-term treatment of chronic, non-cancer pain. And as discussed in the Manufacturers'

thus not preempted, they are nonetheless similarly precluded to the extent they seek to hold the Manufacturers liable under RICO for failure to make certain warnings that the FDA expressly rejected under the FDCA.

In particular, all of Plaintiffs' claims based on the following are preempted (state-law claims) or precluded (federal claims):

1. That the Manufacturers marketed their opioid medications for the long-term treatment of chronic pain.

2. That the Manufacturers marketed their opioid medications to non-cancer patients.

3. That the Manufacturers marketed their opioid medications without advising of dosage ceilings or maximum doses.

4. That the Manufacturers marketed their opioid medications without recommending limitations on duration of use.

5. That the Manufacturers marketed their opioid medications without providing additional warnings related to increased risks with higher doses or longer durations of use.

Second, discovery has made clear that Plaintiffs also premise their claims on a theory that the Manufacturers defrauded the DEA into increasing sales quotas and thus permitting the Manufacturers to sell more opioid medications than justified, thereby causing Plaintiffs harm. But as the U.S. Supreme Court held in *Buckman Co. v. Plaintiffs' Legal Committee*, federal law preempts state-law claims that rest upon fraud on a federal agency because they conflict with the agency's power to "punish and deter fraud" to achieve a "somewhat delicate balance" of federal objectives. 531 U.S. 341, 348 (2001). To the extent that Plaintiffs' state-law claims are premised on a theory that the Manufacturers were able to sell excess opioids by misleading the DEA, they are independently preempted. And given the delicate balance of DEA objectives at issue (i.e.,

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motion for summary judgment for Plaintiffs' failure to offer proof of causation, the marketing and labeling activities of one Manufacturer and/or for one product cannot be imputed to another Manufacturer and/or to another product.

between maintaining effective controls to prevent diversion and ensuring patients access to medication), Plaintiffs' federal RICO claims premised on this theory are similarly precluded.[5]

ARGUMENT

I. PLAINTIFFS' CLAIMS FAIL TO THE EXTENT THEY CONFLICT WITH FDA-APPROVED LABELING AND MARKETING FOR OPIOID MEDICATIONS

As discovery has now shown, Plaintiffs seek to hold the Manufacturers liable for labeling and marketing opioid medications for the long-term treatment of chronic, non-cancer pain; for failing to advise of additional risks of such use; and for failing to recommend dose and duration limitations.[6] But to the extent the Manufacturers marketed their opioid medications for the long-term treatment of chronic, non-cancer pain, the FDA approved that use and rejected the additional labeling changes that Plaintiffs claim should have been made.[7] Thus, federal law preempts Plaintiffs' conflicting state-law claims and precludes their conflicting federal claims.

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[5] The arguments supporting this motion relate to FDA and DEA regulatory requirements applicable to, and authorizing various facets of, the finished drug products that are the subject of this litigation. Noramco is an active pharmaceutical ingredient supplier and not a finished drug product manufacturer. Nevertheless, Plaintiffs have lumped Noramco together with J&J and its other affiliated entities, all Marketing Defendants, or all Defendants collectively, even though it did not manufacture, package, brand, market, promote, distribute or sell the finished drug products that are at issue in this litigation. Noramco joins this motion, because federal preemption of claims addressing finished drug products necessarily requires preemption of claims addressing ingredients (manufactured by Noramco) that are incorporated into such products, and because Noramco is subject to an additional layer of FDA requirements authorizing the use and composition of its ingredients and an additional layer of DEA requirements authorizing the quantity of ingredients that it has manufactured.

[6] Plaintiffs' complaints generally allege that Manufacturers made nine categories of misrepresentations. *See* Third Am. Compl. ("*Summit* TAC") at 49-102, ECF No. 1466; Third Am. Compl. ("*Cuyahoga* TAC") at 47-101, ECF No. 1631. Those allegations underlie their RICO claims (Counts I and II), their Ohio Corrupt Practices Act claims (Counts III and IV), their statutory public nuisance claim (Count V), and their common law claims for nuisance (Counts VI), negligence (Count VII), and fraud (Count VIII). *See, e.g.*, *Summit* TAC ¶¶ 880, 883, 891, 917, 942, 945, 956, 963, 990, 1014-15, 1047, 1074-75. Plaintiffs also assert derivative claims for injury through criminal acts (Count IX), unjust enrichment (Count X), and civil conspiracy (Count XI).

[7] And for those opioid medications not approved for the long-term use of chronic, non-cancer pain, Plaintiffs have no evidence that those Manufacturers marketed those products for that use. In addition, it is black-letter law that off-label marketing is not inherently "false or misleading." *United States v. Caronia*, 73 F.3d 149, 165 (2d Cir. 2012), and may be protected by the First Amendment. *Id.* at 169; *see also Sorrell v. IMS Health Inc.*, 564 U.S. 552, 557 (2011); *Ind./Ky./Ohio Reg'l Council of Carpenters Welfare Fund v. Cephalon, Inc.*, No. 13-7167, 2014 WL 2115498, at *6 (E.D. Pa. May 21, 2014) (rejecting claims based upon allegations of off-label promotion).

A. Plaintiffs' State-Law Claims Premised On Inappropriate Marketing And Labeling Are Preempted

Since Plaintiffs filed these cases, the Manufacturers have believed that Plaintiffs were pursuing preempted state-law claims challenging the FDA's approval of opioids as safe and effective for the treatment of chronic, non-cancer pain without dose or duration limitations. *See*, *e.g.*, Mem. of Law in Supp. of Mfr. Defs.' Joint Mot. to Dismiss at 51-55, ECF No. 499-1. But until the parties engaged in discovery, Plaintiffs denied this fact. In opposing motions to dismiss, Plaintiffs repeatedly asserted they did not seek to hold the Manufacturers liable for inadequate labeling or marketing materials consistent with the FDA-approved labeling. *See*, *e.g.*, Pls.' Omnibus Opp'n to Defs.' Mot. to Dismiss ("Pls.' Opp'n") at 116, ECF No. 654 ("Plaintiffs do not challenge the FDA-approved labeling of any of Defendants' products, but rather their false and misleading promotion of these drugs."); *see also id.* at 118. The Court, in ruling, took Plaintiffs at their word and characterized their claims as "not premised upon inappropriate labeling" but rather on "fraudulent marketing in the promotion and sale of [] opioids." R. & R. ("*Summit* R&R") at 50, ECF No. 1025, *adopted by* Op. & Order ("*Summit* Order") at 2, ECF No. 1203. Indeed, because Plaintiffs defeated the Manufacturers' motion to dismiss by asserting that they were *not* seeking to hold the Manufacturers liable for inappropriate labeling and marketing, Plaintiffs are judicially estopped from basing their claims on that theory now.[8]

Even if such claims were not judicially estopped, they are preempted (or precluded as discussed in Section I.B). Notwithstanding Plaintiffs' representations at the pleading stage, it is now abundantly clear that Plaintiffs *are* pursuing preempted claims that challenge FDA-approved

[8] *See*, *e.g.*, *New Hampshire v. Maine*, 532 U.S. 742, 749 (2001) (Judicial estoppel "generally prevents a party from prevailing in one phase of a case on an argument and then relying on a contradictory argument to prevail in another phase."); *Mirando v. U.S. Dep't of Treasury*, 766 F.3d 540, 545-48 (6th Cir. 2014) (granting summary judgment based on judicial estoppel); *Intellivision v. Microsoft Corp.*, 484 F. App'x 616, 618-21 (2d Cir. 2012) (granting summary judgment given inconsistency with representations made during motion to dismiss phase of same case).

labeling for the Manufacturers' opioid medications. As this Court has recognized, the term "labeling" as used in the FDCA broadly encompasses "representations made in marketing materials." *See* R. & R. ("*Muscogee* R&R") at 30, ECF No. 1499, *adopted by* Op. & Order at 2, ECF No. 1680; *see also* 21 U.S.C. § 321(m) (defining "labeling" to include "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article"); *Strayhorn v. Wyeth Pharms., Inc.*, 737 F.3d 378, 394 (6th Cir. 2013) (noting that "advertising and promotional materials are considered labeling" under the FDCA). Discovery has also established that Plaintiffs *are* seeking to hold the Manufacturers liable for promoting their medications for long-term use and for chronic, non-cancer pain—an indication the FDA continues to approve to this day.

Plaintiffs claim the Manufacturers wrongly marketed opioid medications for the treatment of chronic, non-cancer pain. Plaintiffs' experts have testified that the use of opioids for chronic pain is unsafe. *See, e.g.*, Ex. 2 (Report of David T. Courtwright, Ph.D.) at 6 (asserting that "it [is] dangerous to prescribe narcotic drugs to patients suffering from what is now called chronic nonmalignant pain"); *see also* Ex. 3 (Report of Anna Lembke, M.D. ("Lembke Report")) at 21-63 (asserting that drug manufacturers "overstate[d] [the] benefits of long-term use for chronic pain" and understated its risks). And Plaintiffs claim that the Manufacturers wrongly marketed opioid medications for chronic pain. *See*, *e.g.*, *id.*; Ex. 4 (Cuyahoga Cty. Mar. 18, 2019 Replacement Suppl. Resp. & Objs.to Mfr. Defs.' Interrog. ("Cuyahoga Cty. Interrog. Resp.")) at 152, 155, 160; Ex. 5 (Summit Cty., *et al.*, Mar. 4, 2019 Suppl. Resp. & Objs. to Certain of Mfrs.' Interrog. ("Summit Cty. Interrog. Resp.")) at 156-57, 159; Ex. 6 (Deposition of David M. Kessler ("Kessler Dep.")) at 586:12-587:4 (asserting that Manufacturers falsely marketed that opioid medications lead to "improved functionality" and "can be used in a broad range of indications such

as back pain[] [and] osteoarthritis"); Ex. 7 (Expert Report of Matthew Perri III, B.S. Pharm., Ph.D, R.Ph ("Perri Report")) at 132-34 (alleging the Manufacturers improperly marketed that "[o]pioids are effective for, and improve functioning in, patients taking them for long-term and chronic use").

Plaintiffs claim the Manufacturers wrongly marketed opioid medications without dose or duration limitations or warnings. Several of Plaintiffs' experts have testified that opioids are safe only if a maximum daily dosage and maximum treatment duration are observed. *See, e.g.*, Ex. 8 (Report of David S. Egilman, M.D., M.P.H.) at 52 (asserting that Manufacturers propagated the "myth[]" that opioids have "no ceiling dose"); Ex. 9 (Expert Report of David Kessler, M.D.) at 40-79, 129-141 (asserting that the Manufacturers misstated the risks associated with higher doses of opioids); Ex. 3 (Lembke Report) at 63-66 (asserting that Manufacturers made "inaccurate claims as to the levels to which doses can be safely increased" and as to safe duration of use). And Plaintiffs further claim that the Manufacturers wrongly marketed opioid medications without dose or duration limitations or warnings. *See*, *e.g.*, Ex. 10 (Plaintiffs' Nov. 2, 2018 Am. Resp. to First Set of Interrog.) at 6 (claiming Manufacturers misrepresented opioid medications as safe "for use long-term and at high doses"); Kessler Dep. at 238:11-14 (describing as "dangerous" the idea that "you can go to higher doses because this is just tolerance or dependence"); Ex. 4 (Cuyahoga Cty. Interrog. Resp.) at 152, 155, 160; Ex. 5 (Summit Cty. Interrog. Resp.) at 156-59.

In sum, Plaintiffs claim the Manufacturers made the following "false, misleading, unfair and deceptive statements": "'[r]ound the clock' dosing should be used for chronic pain rather than 'as needed' dosing," "[l]ong-term opioid use improves functioning," there is "[n]o maximum dose," and "[o]pioids can be prescribed for any duration without risk." Ex. 4 (Cuyahoga Cty. Interrog. Resp.) at 152-53, 155, 160; Ex. 5 (Summit Cty. Interrog. Resp.) at 156-59, 165.

But Plaintiffs' state-law claims that the Manufacturers mislabeled and mis-marketed opioid

medications for long-term use or for the treatment of chronic, non-cancer pain fail as a matter of law. As this Court previously held, federal law preempts a state-law claim that "seeks to impose upon a manufacturer a duty to warn beyond what the FDA would approve." *Muscogee* R&R at 31. Since the Court issued its decision on Defendants' motions to dismiss, the Supreme Court reinforced this point in *Merck*, 139 S. Ct. 1668 (2019), which made two critical rulings. *First*, the Supreme Court reiterated that where (as here) the FDA is "fully informed" of the "justifications for [a] warning required by state law" and nonetheless provides "clear evidence" that it "would not approve a change to the drug's label to include that warning," the state-law obligation is preempted.[9] *Id.* at 1672 (citing *Wyeth*, 555 U. S. at 571); *see also id.* at 1673 (noting the FDA often disapproves warnings that lack evidentiary support to avoid "'discourag[ing] [the] appropriate use of a beneficial drug'"). *Second*, the Court clarified that the preemption question is "a legal one for the judge, not a jury." *Id.* at 1679. Under this standard, federal law preempts Plaintiffs' state-law claims challenging the Manufacturers' FDA-approved labeling, and marketing materials consistent with that labeling, because there is "clear evidence" that the FDA "would not approve" the changes to those materials that Plaintiffs claim should have been made.

1. In 2013 The FDA Considered And Rejected The Challenges To The Manufacturers' Marketing And Labeling That Plaintiffs Now Assert

In approving the Manufacturers' opioid medications, the FDA necessarily found "substantial evidence that the drug will have the effect it purports or is represented to have" and that the medication would be safe and effective for its indicated uses. *See* 21 U.S.C. § 355(d); *see also In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 239 (3d Cir. 2012) ("To obtain FDA approval, drug companies generally must submit evidence from

[9] As the Supreme Court clarified, the phrase "clear evidence" was *not* intended to incorporate the "clear and convincing" evidentiary standard or the "preponderance of the evidence" standard because the question is "a matter of law for the judge to decide." *Merck v. Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1679 (2019).

clinical trials and other testing that evaluate the drug's risks and benefits and demonstrate that it is safe and effective for all of the indications 'prescribed, recommended, or suggested' on the drug's label." (quoting 21 U.S.C. § 355(d))). The FDA has approved opioid medications for the treatment of chronic pain without additional dose or duration limitations, yet Plaintiffs are arguing that state law dictates that the Manufacturers should not have sold their medications for that approved indication. Plaintiffs' theory runs afoul of Supreme Court precedent, which makes clear that "an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability." *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 488 (2013).

Further, in 2013, the FDA considered many of the challenges that Plaintiffs now raise. The FDA rejected a request to remove approval for chronic, non-cancer pain and declined to require additional warnings or limitations on dose or duration. The prior year, a group calling itself Physicians for Responsible Opioid Prescribing ("PROP") filed a citizen petition with the FDA.[10] PROP argued that the FDA's approved indications for nearly all opioid medications were "overly broad" and "impl[ied] a determination by the FDA that [opioids] are safe and effective for long-term use." Ex. 11 (Prop Petition) at 1. PROP asked the FDA to reevaluate whether opioids are a safe and effective treatment for "chronic non-cancer pain." *Id.* It also sought specific changes to opioid medication labels. *Id.* at 2 (petitioning the agency to add a "maximum daily dose" and a "maximum duration . . . for continuous (daily) use").

In response, the FDA undertook a comprehensive review of the safety and efficacy of opioid medications as a long-term treatment for chronic pain.[11] For more than a year, the FDA

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[10] *See* Ex. 11 (July 25, 2012 Letter from PROP to FDA ("PROP Petition")) at 1.

[11] *See* Ex. 12 (Sept. 10, 2013 Letter from FDA to PROP ("FDA Resp.")) at 1. FDA specifically rejected the distinction between cancer-related and "non-cancer" chronic pain, explaining that "a patient without cancer, like a patient with cancer, may suffer from chronic pain" and that the agency "knows of no physiological or pharmacological basis upon which to differentiate" between the two. *Id.* at 9.

"carefully reviewed" the issues presented in the PROP petition, held scientific public meetings, considered presentations from dozens of stakeholders, reviewed over 2,500 public comments, and examined the relevant scientific literature. FDA Resp. at 1, 4-6. Upon completion of this review, the FDA ***rejected*** nearly all of PROP's requests. After noting that "the majority of [public] comments opposed PROP's requests," *id.* at 5, the FDA kept extended-release and long-acting opioids indicated for the treatment of chronic pain, with only certain labeling changes intended to "better enable[] prescribers to make decisions based on a patient's individual needs." *Id.* at 8. With just those changes, rather than the changes PROP requested, the FDA determined the labels were adequate to address the risks of misuse, abuse, addiction, overdose, and death. *Id.* at 7.

The FDA also specifically rejected PROP's requests to impose maximum dose and duration requirements, concluding that a "'one-size-fits-all' approach . . . would be problematic and inconsistent with the need for individualized treatment." *Id.* at 5; *see also id.* at 11-17. Dosage limits were inappropriate, the agency explained, because "adverse events and substance abuse" can "occur at high doses" but "can also occur at doses less than" PROP's proposed dosage threshold. *Id.* at 12. Similarly, "limiting the duration of use for opioid therapy" was "not supportable," given the "inconclusive" findings of PROP's scientific studies. *Id.* at 14-15. The FDA specifically acknowledged that the available data demonstrated only "an association—though not necessarily a causal relationship—between opioid dose and certain serious risks of opioid use." *Id.* at 10; *see also id.* at 13 ("[T]he available information does not demonstrate that the relationship is necessarily a causal one.").

By specifically considering and rejecting PROP's demand that opioids be deemed "neither safe nor effective" for long-term treatment of chronic pain, PROP Petition at 1, the FDA's response provides "clear evidence" that the agency would have rejected a change to the labeling regarding

that FDA-approved use.[12] *See Merck*, 139 S. Ct. at 1684 ("[I]f the FDA declines to require a label change despite having received and considered information regarding a new risk, the logical conclusion is that the FDA determined that a label change was unjustified."); *Cerveny v. Aventis, Inc.*, 855 F.3d 1091, 1102 (10th Cir. 2017) ("FDA views overwarnings as problematic because they can render the warnings useless and discourage use of beneficial medications."). In *Cerveny*, as here, the FDA had rejected a Citizen Petition that raised similar concerns about the labeling for Clomid. The Tenth Circuit found that "the rejection of a citizen petition may constitute clear evidence that the FDA would have rejected a manufacturer-initiated change to a drug label." *Id.* at 1105. Similarly, the FDA's response is "clear evidence" that it would have rejected a labeling change to add indicating a dosage ceiling or a maximum treatment duration. *See id.* And, because there was insufficient scientific evidence to find a "causal relationship" between higher doses or longer treatment and increased risk, the Manufacturers could not have made that change on their own. As the Court reaffirmed in *Merck*, manufacturers may change labeling without prior FDA approval only "to 'add or strengthen a . . . warning' where there is 'newly acquired information about the 'evidence of a causal association' between the drug and a risk of harm. 21 CFR §314.70(c)(6)(iii)(A)." *Merck*, 139 S.Ct. at 1673.

And yet, as discovery has now shown, Plaintiffs do seek to hold the Manufacturers liable under state law for not having made those precise labeling changes and for marketing opioid medications consistent with FDA approval. *See supra* at 4-7. Plaintiffs claim the Manufacturers are liable because they did not include in their labeling or promotional material stronger warnings of the risks associated with the long-term use of opioid medications and with the use of opioid

[12] It is irrelevant that the attempt to strengthen labeling initiated with a third party like PROP as opposed to a Manufacturer. Indeed, as Justice Alito noted in his concurrence in *Merck*, the key point is that the FDA considered the evidence and expressly rejected the requested change. *See Merck*, 139 S.Ct. at 1684-85 (Alito, J., concurring).

medications for treating chronic pain (i.e., addiction, withdrawal, interference with functioning, and abuse). Because that is *precisely* the argument that PROP made in its 2012 Petition (*see* Ex. 11 (PROP Petition) at 1), and because the FDA rejected those changes in a detailed and thorough response (*see* Ex. 12 (FDA Resp.) at 6-8), the evidence is "clear" that the FDA would have rejected any attempt to "correct" what Plaintiffs now allege to be "misrepresentations" in the Manufacturers' marketing materials. All of Plaintiffs' state-law claims are preempted for this reason.[13]

Indeed, a North Dakota court recently reached the same conclusion, in the State of North Dakota's case against Purdue, on the ground that North Dakota sought "to impose liability for lawful promotion of FDA-approved medications for an FDA-approved use." Ex. 13 (Order Granting Defs.' Mot. to Dismiss ¶ 16, *State v. Purdue Pharma L.P.*, Case No. 08-2018-CV-01300 (N.D. Dist. Ct. May 10, 2019)). As Plaintiffs do here, North Dakota challenged Purdue's statements regarding the "long-term treatment of chronic pain" and "maximum dosing" for opioids. *Id.* ¶ 27. Over the State's insistence that it was "not pursuing an inadequate labeling theory," the court relied on the FDA's 2013 response to the PROP Petition as "clear evidence" that the FDA would have rejected the State's proposed labeling changes. *Id.* ¶¶ 28-31. The court concluded that the state-law claims were preempted by federal law and rejected the same alleged product claims criticized by Plaintiffs here, including: (1) OxyContin's 12-hour relief; (2) a dosage ceiling for opioids; (3) so-called "pseudoaddiction"; (4) the manageability of addiction risk; (5) withdrawal; and (6) abuse-deterrent formulations. *Id.* ¶¶ 31–37. This Court should do the same.

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[13] In a related case, this Court rejected a preemption argument based on the PROP Petition, concluding that "substantial questions of fact" precluded the Court from assessing the preemptive effect of FDA's response. *See, e.g.*, *Muscogee* R&R at 33-34 (citing *In re Fosamax Prods. Liability Litig.*, 852 F.3d 268 (3d. Cir. 2017), *vacated by Merck*, 139 S. Ct. at 1680-81). But as *Merck* has since made clear, the question of preemption is one of law for a judge to decide, even if it involves factual questions that are "part and parcel of the broader legal question." 139 S. Ct. at 1680.

2. In May 2019, The FDA Reiterated That It Disagrees With The Labeling Changes That Plaintiffs Claim Were Necessary

Although the PROP Petition alone provides sufficient evidence for the Court to conclude that Plaintiffs' state-law marketing and labeling claims are preempted, the FDA has since made clear that it disagrees with the very labeling changes that Plaintiffs assert the Manufacturers should have made. *See Merck*, 139 S. Ct. at 1672. On May 13, 2019, the FDA stated that opioid medications "provide clinically significant analgesic benefit, including for pain for which other analgesics are inadequate." *See* Ex. 1 (May 2019 FDA Mem.) at 9. The FDA also concluded that "most analgesics have no maximum dose because there is no ceiling effect for analgesia," and that "over time some patients may require increases in their dose" due not only to the "development of tolerance" but also to "worsening in the underlying pain." *Id.* at 10. The FDA created a Best Practices in Pain Management Task Force that met in May 2019 to identify "best practices for acute and chronic pain management." *Id.* at 12. This Task Force "*did not recommend* any absolute limits on the individual dose or total daily dose of opioid analgesics" and instead concluded that "emphasis should be placed on the importance of individualized care." *Id.* It also noted that "[a]buse and addiction are separate and distinct from physical dependence and tolerance." *Id.*

These statements provide further clear evidence that the FDA disagrees with Plaintiffs' contention that the Manufacturers misrepresented the benefits of long-term opioid use, of proper dosing for opioid medications, and of opioid use for chronic, non-cancer pain. As recently as *last month*, the FDA rejected the notions that opioids are generally unsafe; that opioid treatment should be subject to dosage and duration limits; and that opioids are never the safest and most effective treatment for chronic pain. *Id.* at 9-12. Because these are the very notions underlying Plaintiffs' state-law claims, federal law preempts those claims.

B. Plaintiffs' RICO Claims Premised On Inappropriate Marketing And Labeling Are Precluded

Plaintiffs' RICO claims are based on the same allegations of inappropriate marketing and labeling that underlie their state-law claims. *See supra* at 4-7; Summit TAC ¶¶ 880, 883; Cuyahoga TAC ¶¶ 923, 926. But a federal statutory claim is precluded when it conflicts with, rather than complements, another federal statute. *See POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 115 (2014).[14] In analyzing preclusion, preemption "principles are instructive insofar as they are designed to assess the interaction of laws bearing on the same subject." *Id.* at 111-12. Under this standard, Plaintiffs' RICO claims are precluded for the same reasons that their state-law claims are preempted. Namely, Plaintiffs seek to impose liability under RICO for the Manufacturers' failure to make certain warnings that the FDA expressly rejected under the FDCA. *See supra* at 8-13. Far from creating "synergies among multiple methods of regulation," *POM*, 573 U.S. at 116, the RICO claims would place the two statutes in direct conflict and permit an end-run around the FDCA's careful regulatory scheme. Plaintiffs' RICO claims are thus precluded by the FDCA.[15]

II. PLAINTIFFS' CLAIMS FAIL TO THE EXTENT THEY TURN ON SHOWING THE MANUFACTURERS DEFRAUDED THE DEA

Plaintiffs also assert that the Manufacturers made misrepresentations to the DEA in order

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[14] *POM Wonderful* addressed whether the FDCA precluded a Lanham Act claim. 573 U.S. at 106. While the Court found that the claim was not precluded, the outcome is distinguishable. *POM Wonderful* found that the two federal statutes at issue there addressed different concerns and therefore did not conflict. *Id.* at 115 (Lanham Act claim sought to protect commercial interests whereas the FDCA protects public health and safety). Here, in contrast, Plaintiffs seek to use RICO to punish alleged public health "violations"—which were approved by the FDA—and thus to disrupt the regulatory balance created by the FDCA to both protect and promote public health.

[15] Further, even if Manufacturers had made the warnings that Plaintiffs now claim were required under the federal mail and wire fraud statutes (the alleged predicate offenses underlying Plaintiffs' RICO claims), the FDA would have rejected them, as the PROP Petition establishes. Thus, the FDA's decisions create "a break in the causal chain between the alleged misstatements" and Plaintiffs' asserted injuries. *United States ex rel. Nargol v. DePuy Orthopaedics, Inc.*, 865 F.3d 29, 34 (1st Cir. 2017), *cert. denied sub nom. Med. Device Bus. Servs., Inc. v. United States ex rel. Nargol*, 138 S. Ct. 1551 (2018).

to convince the DEA to set inappropriately high quotas for the amount of opioid medications that the Manufacturers could legally sell. As a result of those higher quotas, Plaintiffs claim that the Manufacturers were able to sell more opioid medications, resulting in eventual harm to Plaintiffs. But under the logic of the U.S. Supreme Court's decision in *Buckman*, federal law preempts Plaintiffs' state-law claims based on a fraud-on-the-DEA theory. 531 U.S. at 343. And Plaintiffs' federal RICO claims are precluded.

A. Plaintiffs' State-Law Claims Premised Upon Fraud On The DEA Are Preempted

In their complaints, Plaintiffs alleged that the CSA requires the Manufacturers to "limit sales [of opioid medications] within a quota set by the DEA for the overall production of Schedule II substances like opioids." Summit TAC ¶ 507; Cuyahoga TAC ¶ 491; *see also* Summit TAC ¶¶ 508-09; Cuyahoga TAC ¶¶ 492-93. In order to increase their sales of opioid medications, Plaintiffs claim that the Manufacturers set out to "fraudulently increas[e] the quotas" set by the DEA. Summit TAC ¶¶ 526, 761, 855, 961, 965, 968; Cuyahoga TAC ¶¶ 510, 807, 898, 1003, 1007, 1010; *see also* Summit TAC ¶¶ 548-50, 854; Cuyahoga TAC ¶¶ 531-33, 897. Plaintiffs allege that the Manufacturers defrauded the DEA into setting "artificially high" quotas by "control[ling] the flow of information" to the DEA and "ensur[ing] that suspicious orders were not reported to the DEA." Summit TAC ¶¶ 549-50, 766; Cuyahoga TAC ¶¶ 532-33, 812; *see also Marsh v. Genentech, Inc.*, 693 F.3d 546, 553 (6th Cir. 2012) (noting that "failure to submit reports" to federal agency as required is an allegation of fraud on the agency). When ruling on the motions to dismiss, the Court acknowledged that Plaintiffs were asserting a fraud-on-the-DEA theory of liability. *See Summit* Order at 8, 21; *Summit* R&R at 9, 43, 97. Indeed, the Court found that Plaintiffs' theory of "but-for" causation turned on allegations of the "systemic undermining of quotas" set by the DEA. *See Summit* R&R at 26.

As discovery has now confirmed, Plaintiffs seek to prove their fraud-on-the-DEA theory by proving that the Manufacturers made material misrepresentations and omissions to the DEA, convinced the DEA to set artificially high sales quotas, and then sold improper quantities of opioids to Plaintiffs' detriment.[16] Plaintiffs claim that the Manufacturers sought to increase sales by "fraudulently increasing the quotas" set by the DEA. Ex. 14 (Pls.' Dec. 28, 2018 Suppl. Objs. & Resp. to Mfr Defs.' Interrog. Nos. 28/29) ¶¶ 4, 7, 30; *see also id.* ¶¶ 5-6, 13, 24-27, 30-31, 35, 38, 39, 41, 45. For example, according to Plaintiffs, certain Manufacturers allegedly "disseminated false and misleading statements" to the DEA that the quotas "should be increased," that they "were complying with their obligations to maintain effective controls against diversion" and "notify the DEA of any suspicious orders or diversion," and that "they did not have the capability to identify suspicious orders." *Id.* ¶ 32; *see also id.* at ¶ 34. The Manufacturers also allegedly "applied political and other pressures on the . . . DEA to halt prosecutions for failure to report suspicious orders." *Id.* ¶ 33. Plaintiffs' expert Lacey Keller asserts that the Manufacturers failed to report to the DEA "millions of prescriptions and purchases of billions of dosage units . . . of unusual size or frequency." Ex. 15 (Expert Analysis: Lacey R. Keller) at 9-10 (¶ 27); *see also id.* at 10-11 (¶¶ 32-33). Plaintiffs' DEA expert James Rafalski concludes that the Manufacturers' "failures to comply with the Requirements of the [CSA] . . . led to the excess quantity of opiate pills flooding the illicit market." Ex. 16 (James E. Rafalski, Analysis of Distributor and Manufacturer Regulatory Compliance) at 46.

But Plaintiffs' state-law claims based on a fraud-on-the-DEA theory are preempted under the CSA. In *Buckman*, plaintiffs claimed that they suffered injury from medical devices that would not have been approved but-for the manufacturer's misrepresentations to the FDA. 531

[16] Plaintiffs have no evidence to support these claims, but they would be preempted at any rate.

U.S. at 343. The Supreme Court found that the FDCA preempted plaintiffs' state-law claims. *Id.* The Court noted that "[p]olicing fraud against federal agencies is hardly a field which the States have traditionally occupied, such as to warrant a presumption against finding federal pre-emption of a state-law cause of action. To the contrary, the relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law." *Id.* at 347.

In light of this framework, the *Buckman* Court found that the fraud-on-the-FDA claims were preempted. *Id.* at 348. The conflict between state and federal law "stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the [FDA]." *Id.* at 348. The FDA is "empowered to require additional necessary information" from manufacturers and "to investigate suspected fraud" and "has at its disposal a variety of enforcement options that allow it to make a measured response to suspected fraud upon the [FDA]." *Id.* at 348-49. The Court found that "[t]his flexibility is a critical component of the statutory and regulatory framework under which the FDA pursues difficult (and often competing) objectives," including evaluating the safety of medical devices, policing fraud, and not interfering with the decisions of healthcare providers. *Id.* at 349-50. The FDA uses its authority "to achieve a somewhat delicate balance" of those objectives, and that delicate balance "can be skewed by allowing fraud-on-the-FDA claims under state tort law." *Id.* at 348. Such claims would also "dramatically increase the burdens facing potential applicants," "deter" otherwise-permissible uses of medical devices, and incentivize manufacturers to "submit a deluge of information that the [FDA] neither wants nor needs." *Id.* at 350-51. In sum, "[s]tate-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the [FDA's] judgment and objectives." *Id.* at 350.

Buckman has been widely applied to claims of fraud on agencies other than the FDA,[17] and the logic, reasoning, and holding of *Buckman* apply with full force here.[18] Plaintiffs are counties, and thus their attempt to "[p]olic[e] fraud" against the DEA does not "warrant a presumption against finding federal pre-emption of a state-law cause of action." *Buckman*, 531 U.S. at 347. Further, state and federal law conflict here because the CSA "empowers the [DEA] to punish and deter fraud against the [DEA]." *See id.* at 348. Like the FDA, the DEA is "empowered to require additional necessary information" from the Manufacturers. *See*, *e.g.*, 21 U.S.C. § 823 (listing registration requirements); 21 U.S.C. § 826(c) (requiring the federal government to set and revise quotas, "upon application therefor by a registered manufacturer"); 21 U.S.C. § 827 (requiring periodic reporting); *see also* 21 U.S.C. §§ 821, 822; 21 C.F.R. §§ 1301.11-1301.19 (listing registration requirements); 21 C.F.R. § 1301.31 (permitting inspection of registrants); 21 C.F.R. 1301.37 (permitting orders to show cause).

The DEA is also "empowered to investigate suspected fraud" and "has at its disposal a variety of enforcement options that allow it to make a measured response to suspected fraud upon the [DEA]." *Buckman*, 531 U.S. at 348-49; *see*, *e.g.*, 21 U.S.C. § 842 (making it unlawful for a manufacturer to sell a controlled substance not authorized by a Section 826 quota or in excess of a quota or to fail to make required reports, and imposing penalties); 21 U.S.C. § 843

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[17] *See*, *e.g.*, *Nathan Kimmel, Inc. v. DowElanco*, 275 F.3d 1199 (9th Cir. 2002) (fraud-on-the-EPA); *Offshore Serv. Vessels, L.L.C. v. Surf Subsea, Inc.*, C.A. No. 12-1311, 2012 WL 8021738 (E.D. La. Oct. 17, 2012) (fraud-on-the-Coast Guard); *Morgan v. Brush Wellman, Inc.*, 165 F. Supp. 2d 704, 722 (E.D. Tenn. 2001) (fraud-on-the-Dep't of Energy); *Williams v. Dow Chem. Co.*, 255 F. Supp. 2d 219, 232 (S.D.N.Y. 2003) (fraud-on-the-EPA); *Redelmann v. Alexander Chem. Corp.*, No. 98-L-12350, 2002 WL 34423377 (Ill. Cir. July 26, 2002) (fraud-on-the-EPA); *see also Transmission Agency of N. Cal. v. Sierra Pac. Power Co.*, 295 F.3d 918, 932 n.10 (9th Cir. 2002) (fraud-on-the-FERC); *Murray v. Motorola, Inc.*, 982 A.2d 764, 770 n.6 (D.C. 2009) (fraud-on-the-FCC).

[18] The CSA provides that state-law claims are preempted when "there is a positive conflict" such that the CSA and state law "cannot consistently stand together." 21 U.S.C. § 903. And regardless, *Buckman* makes clear that "ordinary pre-emption principles apply" whether or not an express preemption provision exists or even whether or not an express saving clause attempts to bar operation of conflict preemption principles. 531 U.S. at 352.

(making it unlawful "knowingly or intentionally . . . to furnish false or fraudulent material information in, or omit any material information from, any application, report, record or other document required to be made, kept, or filed . . . ," and imposing criminal penalties and permitting civil actions for injunctions); 21 U.S.C. §§ 875-883 (granting federal government authority to investigate and seek relief for violations of CSA); 21 C.F.R. § 1301.36 (permitting suspension or revocation of registration); 21 C.F.R. §§ 1301.41-1301.46 (authorizing hearings).

Thus, like the FDA in the context of medical devices, the DEA "is charged with the difficult task of regulating the . . . distribution of [controlled substances] without intruding upon decisions statutorily committed to the discretion of health care professionals." *See Buckman*, 531 U.S. at 350. The DEA seeks to strike a "delicate balance" (*see id.* at 341) between ensuring access to beneficial medications while preventing illegal sales. *See* 21 U.S.C. § 801 (noting both the "useful and legitimate medical purpose" of controlled substances "to maintain the health and general welfare of the American people" as well as the "substantial and detrimental effect" of illegal sales). This balance would "be skewed by allowing state-law fraud-on-the-[DEA] claims." *See Buckman*, 531 U.S. at 341; *see also McDaniel v. Upsher-Smith Labs., Inc.*, 893 F.3d 941, 948 (6th Cir. 2018).

Plaintiffs' claims would also "dramatically increase the burdens" on the Manufacturers. *See Buckman*, 531 U.S. at 350. The Manufacturers would be forced to comply with the DEA's "detailed regulatory regime in the shadow of 50 States' tort regimes." *See id.* And they would be led "to fear that their disclosures" to the DEA "will later be judged insufficient in state court," incentivizing them "to submit a deluge of information" that the DEA "neither wants nor needs." *See id.*, 531 U.S. at 350-52. In sum, Plaintiffs' "[s]tate-law fraud-on-the-[DEA] claims inevitably conflict with the [DEA's] responsibility to police fraud consistently with the [DEA's]

judgment and objectives." *See id.* at 350; *see also Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961, 966 (6th Cir. 2004).

Indeed, this Court has already indicated that fraud-on-the-DEA claims should be preempted. In ruling on motions to dismiss in *The Muscogee (Creek) Nation v. Purdue Pharma L.P., et al.*, the Court found that the Muscogee Nation's claims were "not premised on a fraud upon the DEA, and thus do not run afoul of *Buckman* . . . ." No. 1:17-md-02804, 2019 WL 2468267, at *22 (N.D. Ohio Apr. 1, 2019), *adopted by* Op. & Order, ECF No. 1203, at 2; *see Summit* Order at 8, 21; *Summit* R&R at 9, 43, 97. But here, discovery has made clear that Plaintiffs' state-law claims are undisputedly "premised on a fraud upon the DEA" and thus do "run afoul of *Buckman*." *See Muscogee*, 2019 WL 2468267, at *22; *see also McDaniel v. Upshur-Smith Labs.*, 893 F.3d 941, 947-48 (6th Cir. 2018) (state-law claims against pharmaceutical manufacturer preempted because violation of federal law was "critical" to claims); *Marsh v. Genentech, Inc.*, 693 F.3d 546, 553-54 (6th Cir. 2012). Plaintiffs' state-law claims are preempted because they are premised upon a fraud on the DEA.

B. Plaintiffs' RICO Claims Premised Upon Fraud On The DEA Are Precluded

Plaintiffs' RICO claims are similarly precluded to the extent that they rely on allegations of fraud on the DEA. *See supra* at 14-20. The policy considerations cited in *Buckman* have been directly applied to preclude a federal statutory claim. *See United States ex rel Dan Abrams Co. LLC v. Medtronic, Inc.*, No. LA CV15-01212-JAK (ASx), 2017 WL 4023092, at *7 (C.D. Cal. Sept. 11, 2017) (following *Buckman* and precluding federal False Claims Act premised on fraud-on-the-FDA); *see also POM Wonderful*, 573 U.S. at 112 (noting that preemption principles are "instructive" when assessing one federal statute's preclusive effect on another). As explained in more detail above, the CSA "empowers the [DEA] to punish and deter fraud" and charges the DEA with "the difficult task of regulating the . . . distribution" of controlled substances and

striking a "delicate balance" between the need to ensure access to beneficial medications and the need to deter abuse. *Buckman*, 531 U.S. at 348, 350. Because Plaintiffs' RICO claims would upset this delicate balance, "the policy concerns expressed in *Buckman* are material here," *Medtronic,* 2017 WL 4023092, at *7, and preclude Plaintiffs' RICO claims.

CONCLUSION

For the foregoing reasons, the Court should grant the Manufacturers' motion for summary judgment and grant such additional relief as it deems just and proper.

Dated: June 28, 2019

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LOCAL RULE 7.1(F) CERTIFICATION

I hereby certify that this case has been assigned to the "litigation track" and that this Memorandum adheres to the page limitations set forth in the Amended Order Regarding Pretrial Motions for "Track One" Trial (ECF No. 1709) and L.R. 7.1(f).

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CERTIFICATE OF SERVICE

I hereby certify that on June 28, 2019, a copy of the foregoing Manufacturer Defendants' Memorandum of Law in Support of Motion for Summary Judgment that Plaintiffs' State-Law Claims Are Preempted and Their Federal Claims Are Precluded has been served on the Parties, the Court, and the Special Masters pursuant to the Directions Regarding Filing of Briefs Under Seal (ECF No. 1719).

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